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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,071	10/30/2000	Ester Fride	7754-071	6091

28765 7590 11/19/2002

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PATENT DEPARTMENT
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EXAMINER

BARTS, SAMUEL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 11/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/698,071

Applicant(s)

FRIDE ET AL.

Examiner

Samuel A Barts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8 and 18-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 6, 7, and 21-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions useful in treating and managing the various claimed maladies, does not reasonably provide enablement for composition useful in preventing the same maladies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prevent a disease such as hypertension. The numerous pathways of causing hypertension in humans range from hereditary factors, diet, and weight to list a few. It is not reasonable to believe that a single compound could prevent a disease, such as hypertension, which is clearly derived from many different biological pathways. The claims are not commensurate in scope with support provided in the specification and thus should be amended by removing the word prevention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 4 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 defines limitations to a variable labeled "Q". This variable was in the original claim 1 but not in the newly amended claim 1. The claim is confusing and indefinite. Correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

513 6. Claims 1-3, 6-7, and 17-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al (US 5,434,295) (09/698,071).

The instant claimed invention is directed to the compound labeled HU-308 and pharmaceutical compositions of said compound with the requirement that the compound/composition have the (3S,4S) configuration, and be essentially free of the (3R,4R) enantiomers.

Mechoulam et al teach a genus of compounds that are useful for treating various pathological conditions associated with damage to the central nervous system. The compounds within the genus are further contemplated to have the

(3S,4S) configuration, and be essentially free of the (3R,4R) enantiomers. See column 3 lines 42-46. The exemplified species in Mechoulam et al are not far removed from the instant claimed compound. See for example HU-255.

Mechoulam et al generically teach the instant claimed compound in column 3 lines 10-46. Specifically note the definitions of variables in lines 30-38.

Thus the instant claimed invention differs from the prior art as being directed to a subgenus. The disclosure of Mechoulam et al suggests the compounds within the genus to be useful for treating conditions associated with damage to the central nervous system.

It would have been obvious to one having ordinary skill in the art at the time that applicants invention was made to select other compounds, including the compound HU-308, from the genus of Mechoulam et al with a reasonable expectation that the compounds would be useful for treating conditions associated with damage to the central nervous system.

One skilled in the art would be motivated to make such a change in order to make other compounds which would be expected to be useful for treating conditions associated with damage to the central nervous system.

Applicants have suggested that the compound HU-308 has unexpected results. That claim has not been sufficiently demonstrated. If applicant believes that HU-308 has unexpected properties he is invited to provide a side-by-side


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comparison to the closest prior art compound. The comparison should also be commensurate in scope with the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A Barts whose telephone number is 703-308-4630. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johan Richter can be reached on 308-1235. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Samuel A Barts
Primary Examiner
Art Unit 1621

s.b.

November 18, 2002